

conditions include a hybridisation and/or a wash carried out in 0.2xSSC-2xSSC buffer, 0.1% (w/v) SDS at 42°C to 65°C.

78. (New) The isolated nucleic acid molecule of claim 59, wherein the hybridisation conditions are high stringency, said conditions comprising a hybridisation and/or a wash carried out in 0.1xSSC-0.2xSSC buffer, 0.1% (w/v) SDS at a temperature of at least 55°C.

### REMARKS

Claims 1-39 have been canceled without prejudice, and new claims 40-78 have been presented herein. The new claims are supported by the as-filed claims and the as-filed Specification. The incorporation of certain stringency conditions is supported by the as-filed and substitute specifications. None of the amendments made herein constitutes the addition of new matter.

#### The Interview

Applicants appreciate the courtesy extended by the Examiner in the interview of June 27, 2002.

#### The Formal Drawings

In response to requirements of the Patent and Trademark Office, Applicants have provided Formal Drawings for entry into the present application.

#### The Requirement for Restriction

Claims 30 and 34-39 have been canceled without prejudice, and their subject matter is not presented in the new claims. Applicants will attend to any further cancellation and/or amendment of claims as necessary when this application is otherwise in condition for allowance. Applicants respectfully request that with the allowability of the claims specifying SEQ ID NO:10 and sequences having the specified percent identity thereto, that the extent of

examination be expanded with respect to DNA sequences related to EcR coding sequences, vectors, host cells, method of hybridization. Applicants acknowledge that sequences of SEQ ID NO:10 and sequences encoding an ecdysteroid receptor which binds ecdysone, where the sequence is 60% identical to SEQ ID NO:10 are under consideration.

The Rejections under 35 U.S.C. 112, first paragraph

Claims 1-7, 9, 12-18, 20, 22-29 and 31-32 have been rejected under 35 U.S.C. 112, first paragraph, as allegedly for coding sequences of 40% or greater nucleotide sequence homology to SEQ ID NO:10. Applicants respectfully traverse this rejection.

In the interest of advancing prosecution and without acquiescing to this rejection, Applicants have amended the claims to recite those sequences having at least 60% sequence identity to SEQ ID NO:10 and to specify that the encoded protein is an ecdysteroid receptor polypeptide which binds ecdysone. This limitation was discussed in the personal interview of June 27, 2002, and it is Applicants' understanding that this level of sequence identity is acceptable to the Patent Office. In view of the high level of skill in the relevant art, the well known techniques for identifying sequences with the specified relatedness to the specific sequence, and the readily accessible methods for testing a protein for ligand binding (e.g., ecdysone binding), Applicants respectfully urge that the invention as claimed is adequately enabled by the as-filed Specification, taken with what is well known and readily accessible in the art.

Claims 1-7, 9, 12-18, 20, 22-29 and 31-32 have been rejected under 35 U.S.C. 112, first paragraph, with the Patent Office alleging containing subject matter which was not described in the Specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the invention. Applicants respectfully traverse this rejection.

It has been alleged that there are genus claims, including deletion, substitution, addition mutations, but that the Specification and claims do not indicate the distinguishing attributes of the genus. Applicants respectfully note that the Specification clearly indicates that the encoded EcR proteins bind ecdysteroids, e.g., ecdysone. The methods for confirming ligand binding in such a situation are well known to the art. In the interest of advancing prosecution, Applicants have added specific recitation related to ecdysone binding in the claims.

Claims 1-7, 9, 12-18, 20, 22-29 and 31-32 have been rejected as allegedly containing subject matter which was not described in the Specification in an enabling manner. Applicants respectfully traverse this rejection.

The Patent Office has opined that a deposit is necessary for enablement of the present invention. The Patent Office requires that Applicants (or their agent) provide a declaration related to compliance with the provisions of statute.

Applicants respectfully note that there is abundant sequence disclosure in the present application. While there has been a deposit made in accordance with the provisions of the Budapest Treaty, Applicants respectfully argue that one of ordinary skill in the art could practice the present invention without obtaining the deposited strain(s). An EcR polypeptide coding sequence could be readily synthesized using the sequence information provided, for example, that of SEQ ID NO:10, and that coding sequence could be incorporated into a cloning vector of interest using techniques and materials well known to the art.

In the interest of advancing prosecution, the undersigned states on behalf of Applicants that the deposited strains were deposited in a recognized depository under the provisions of the Budapest Treaty, that all restrictions on the availability of the deposited strain to the public will be irrevocably removed upon the grant of a patent, that the deposited biological materials have been deposited under conditions allowing access to the material during the pendency of the application to one determined by the United States Commissioner of Patents and Trademarks

under 37 C.F.R. 1.14 and 35 U.S.C. 122, and that if the depository requires a replacement of the deposited biological materials that Applicants will replace the deposited biological materials for at least the term of a patent or a term of 30 years from the original deposit and at least 5 years after the most recent request for the furnishing of a deposit.

In view of the amendments and the foregoing discussion, Applicants respectfully request the withdrawal of the rejections under 35 U.S.C. 112, first paragraph.

The Rejections under 35 U.S.C. 112, second paragraph

Claims 1-7, 9, 12-18, 20, 22-29 and 31-32 have been rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite. Applicants respectfully traverse this rejection.

Claims 1, 4, 8 and 10-15 are allegedly indefinite in the recitation of "EcR" and "USP". Applicants have written the corresponding new claims to define these acronyms.

Claim 6 is allegedly indefinite in the recitation of "close relative". In the interest of advancing prosecution and without acquiescing to this rejection, Applicants have not included this recitation in the claims presented herein. Applicants do not relinquish their position that EcR sequences with at least 60% sequence identity to SEQ ID NO:10 are within the scope of the invention.

Claims 1, 7, 12, 17, 22 and 25 have been rejected as allegedly indefinite in the recitation of "bioactive analogue". Applicants have included language in the relevant new claims to specify that the EcR polypeptides bind ecdysone, a representative insect ecdysteroid.

Claims 22-23 and 25-27 have been rejected as allegedly indefinite in the recitation of "hybridisation effective amount". Applicants respectfully maintain there is no indefiniteness with respect to this term. One of ordinary skill in the art understands that a hybridization effective amount is one which allows hybridization of related sequences under the relevant

hybridization conditions. In the interest of advancing prosecution and without acquiescing to the present rejection, Applicants have incorporated a description of low, medium and high stringency hybridization conditions. This description is supported by page 25, lines 10-20, with reference to the substitute specification.

In view of the clarifications provided herein and the amendments to the claims, Applicants respectfully request the withdrawal of the rejections under 35 U.S.C. 112, second paragraph.

#### The Rejections under 35 U.S.C. 102

Claims 1-7, 9, 12-18, 20, 22-29 and 31-32 have been rejected under 35 U.S.C. 102(b) as allegedly anticipated by Mouillet et al. (1997).

The Examiner has indicated that the cited Mouillet et al. reference discloses an EcR with 45.5% amino acid sequence identity to the elected sequence.

In the interest of advancing prosecution, Applicants have presented new claims which recite that the claimed sequences have at least 60% sequence identity to the elected sequence (SEQ ID NO:10). The recitation of at least 60% sequence identity is supported by page 22, lines 20-24 of the substitute specification. The content of this passage was not changed from that of the as-filed specification.

In view of the amendments to the claims, Applicants respectfully submit that the invention as now claimed is not anticipated by the cited Mouillet et al. reference, and the rejection must be withdrawn.

#### Conclusion

In view of the foregoing, it is submitted that this case is in condition for allowance, and passage to issuance is respectfully requested.

If there are any outstanding issues related to patentability, the courtesy of a telephone interview is requested, and the Examiner is invited to call to arrange a mutually convenient time.

This amendment is accompanied by the submission of Formal Drawings, a Petition for Extension of Time (two months) and a check in the amount of \$400.00 as required under 37 C.F.R. 1.17. It is believed that this amendment does not necessitate the payment of any additional fees under 37 C.F.R. 1.16-1.17. If the amount submitted is incorrect, however, please charge any deficiency or credit any overpayment to Deposit Account No. 07-1969.

Respectfully submitted,



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Attorney docket No. 53-99  
bmk: July 22, 2002